K082419

1083

510(k) Summary

MAY 27 2009

Establishment: Intra-Lock International, Inc.
6560 West Rogers Circle
Suite 24
Boca Raton, FL 33487

Proprietary Name: ReOss™ Products

Classification Name: Bone Grafting Materials, 872.3930
Resorbable calcium salt bone void filler device 888.3045

Device Classification: Class II

Predicate Devices:

Granular	*Manufacturer*	*Product Code*	*K#*
Copios BVF	Kensy Nash/Zimmer	MQV	K071237
Eovia	Orthotec	MQV	K040514
OsSatura	Isotis	LYC	K042706
Bioscaff Alvelac	Bio-Scaffold International Pte Ltd.	LYC	K080308
Putty	*Manufacturer*	*Product Code*	*K#*
Stryker TCP	Stryker	MQV	K060061
Optimum DBM	LifeNet	MQV	K053098
Actifuse ABX E-Z fil	Apatec	MQV	K071206
Dynagraft	Isotis	MQV	K040419
Putty	*Manufacturer*	*Product Code*	*K#*
Optimum DBM	LifeNet	MQV	K053098
DynaGraft	Isotis	MQV	K040419

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Material Description:

ReOss™ is a hydrophilic, highly porous, resorbable, synthetic copolymer permeated with osteoconductive sub-micron particles of Hydroxyapatite. It is configured as a multi-pore, three-dimensional scaffold that is engineered to integrate with the physiochemical state of bone tissue.

ReOss™ is available as a Powder, Putty or Reverse Phase Injectable Gel.

ReOss™ Products are provided in sterile packaging in various dosage volumes.

Intended Use:

Dental Applications

ReOss™ Granules are indicated for filling and/or augmenting intraoral/maxillofacial osseous defects, such as intrabony periodontal osseous defects, furcation defects, augmentation of bony defects of the alveolar ridge, filling of tooth extraction sites, and sinus elevation grafting.

Safety and Performance:

This submission is an Abbreviated 510(k) as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), Intra-Lock International has provided information to demonstrate conformity with FDA's guidance document entitled Bone Grafting Materials, 872.3930 and Resorbable calcium salt bone void filler device 888.3045. In addition, theses guidance documents were also consulted during our preparation of this application for permission to market these products.

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Conclusion:

Based on the indications for use, technological characteristics, and comparison to predicate devices, the Intra-Lock ReOss™ products have been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2009

Mr. Jeffery Sakoff
Vice President, Director of Operations
Intra-Lock International, Incorporated
6560 West Rogers Circle, Suite 24
Boca Raton, Florida 33487

Re: K082419
Trade/Device Name: ReOss
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: MQV, LYC
Dated: May 12, 2009
Received: May12, 2009

Dear Mr. Sakoff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

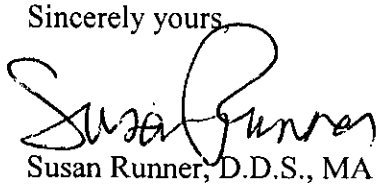
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082419

Indications for Use

510(k) Number (if known): K082419

Device Name: ReOss

Indications For Use:

ReOss™ Powder, Putty and Gel are indicated for filling and/or augmenting intraoral/maxillofacial osseous defects, such as intrabony periodontal osseous defects, furcation defects, augmentation of bony defects of the alveolar ridge, filling of tooth extraction sites, and sinus elevation grafting.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kai Mulay for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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